




PTO/SB/08A (04-03)

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|---|------------------------|--------------------------|-------------------|
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br>(Use as many sheets as necessary) |                        | <b>Complete if Known</b> |                   |
|   |                        | Application Number       | 10/776,657        |
|   |                        | Filing Date              | February 10, 2004 |
|   |                        | First Named Inventor     | SHARMA, Shubh D.  |
|   |                        | Art Unit                 | 1626              |
|   |                        | Examiner Name            |                   |
| Sheet 1 of 6  | Attorney Docket Number | 70025-US04-574           |                   |

| U. S. PATENT DOCUMENTS |          |  |                                |  |   |
|------------------------|----------|--|--------------------------------|--|---|
| Examiner Initials*     | Cite No. | Document Number                          | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|                        |          | Number-Kind Code <sup>2</sup> (if known) |                                |  |   |
| GS                     |          | US- 6,579,968                            | 06-17-2003                     | Blood, et al.                                      |   |
|                        |          | US- 6,534,503                            | 03-18-2003                     | Dines, et al.                                      |   |
|                        |          | US- 6,515,122                            | 02-04-2003                     | Lang, et al.                                       |   |
|                        |          | US- 6,472,398                            | 10-29-2002                     | Palucki, et al.                                    |   |
|                        |          | US- 6,458,790                            | 10-01-2002                     | Palucki, et al.                                    |   |
|                        |          | US- 6,451,783                            | 09-17-2002                     | Hadock, et al.                                     |   |
|                        |          | US- 6,410,548                            | 01-25-2002                     | Nargund, et al.                                    |   |
|                        |          | US- 6,376,509                            | 04-23-2002                     | Bakshi, et al.                                     |   |
|                        |          | US- 6,350,760                            | 02-26-2002                     | Bakshi, et al.                                     |   |
|                        |          | US- 6,284,735                            | 09-04-2001                     | Girten et al.                                      |   |
|                        |          | US- 6,214,831                            | 04-10-2001                     | Yokoo, et al.                                      |   |
|                        |          | US- 6,207,699                            | 03-27-2001                     | Rothman  |   |
|                        |          | US- 6,191,117                            | 02-20-2001                     | Kozachuk   |   |
|                        |          | US- 6,162,805                            | 12-19-2000                     | Hefli  |   |
|                        |          | US- 6,140,354                            | 10-31-2000                     | Dax, et al.  |   |
|                        |          | US- 6,127,424                            | 10-03-2000                     | Martin, et al.                                     |   |
|                        |          | US- 6,033,656                            | 03-07-2000                     | Mikami, et al.                                     |   |
|                        |          | US- 5,965,565                            | 10-12-1999                     | Chen, et al.                                       |   |
|                        |          | US- 5,880,125                            | 03-09-1999                     | Nargund  |   |

| FOREIGN PATENT DOCUMENTS  |          |   |                                |   |   |    |
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| Examiner Initials*  | Cite No. | Foreign Patent Document                     | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | 1* |
|   |          | Country Code* Number* Kind Code* (if known) |                                |   |   |    |
| GS<br> |          | WO 00/40247                                 | 07-13-2000                     | Alizyme Therapeutics                            |   |    |
|   |          | WO 03/009847                                | 02-06-2003                     | Amgen, Inc.                                     |   |    |
|   |          | WO 02/081443                                | 10-17-2003                     | Chiron Corporation                              |   |    |
|   |          | WO 02/059108                                | 08-01-2002                     | Eli Lilly & Company                             |   |    |
|   |          | WO 03/061660                                | 07-31-2003                     | Eli Lilly & Company                             |   |    |
|   |          | WO 01/182210                                | 03-15-2001                     | Genentech, Inc.                                 |   |    |

Package  
1 of 4

|                    |                              |                 |            |
|--------------------|------------------------------|-----------------|------------|
| Examiner Signature | /Golam Shameem/ (09/05/2006) | Date Considered | 09/05/2006 |
|--------------------|------------------------------|-----------------|------------|

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><i>(Use as many sheets as necessary)</i> |             | Application Number       | 10/776,657        |
|  |             | Filing Date              | February 10, 2004 |
|  |             | First Named Inventor     | SHARMA, Shubh D.  |
|  |             | Art Unit                 | 1626              |
|  |             | Examiner Name            |                   |
| Sheet <b>2</b>   | of <b>6</b> | Attorney Docket Number   | 70025-US04-574    |

| U. S. PATENT DOCUMENTS   |                       |  |                                |   |   |
|--|-----------------------|--|--------------------------------|---|---|
| Examiner Initials*   | Cite No. <sup>1</sup> | Document Number                          | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|  |                       | Number-Kind Code <sup>2</sup> (if known) |                                |   |   |
| GS<br>↓<br>↓<br>↓<br>↓<br>↓<br>↓<br>↓<br>↓<br>↓<br>↓<br>↓<br>↓ |                       | US- 5,877,182                            | 03-02-1999                     | Nargund, et al.                                 |   |
|  |                       | US- 5,804,578                            | 09-08-1998                     | Chakravarty, et al.                             |   |
|  |                       | US- 5,721,251                            | 02-24-1998                     | Chen, et al.                                    |   |
|  |                       | US- 5,721,250                            | 02-24-1998                     | Morriello, et al.                               |   |
|  |                       | US- 5,494,919                            | 02-27-1996                     | Morriello, et al.                               |   |
|  |                       | US- 5,120,713                            | 06-09-1992                     | Mugica  |   |
|  |                       | US- 4,937,267                            | 06-26-1990                     | Holloway, et al.                                |   |
|  |                       | US- 4,680,289                            | 07-14-1987                     | Applezweig                                      |   |
|  |                       | US- 4,626,549                            | 12-02-1986                     | Molly, et al.                                   |   |
|  |                       | US- 4,239,763                            | 12-16-1980                     | Milavec, et al.                                 |   |
|  |                       | US- 4,148,923                            | 04-10-1979                     | Guidicelli, et al.                              |   |
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|  |                       | US-                                      |                                |   |   |
|  |                       | US-                                      |                                |   |   |
|  |                       | US-                                      |                                |   |   |
|  |                       | US-                                      |                                |   |   |

| FOREIGN PATENT DOCUMENTS    |                       |   |                                |   |   |                |
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|                             |                       | Country Code <sup>4</sup> -Number <sup>5</sup> -Kind Code <sup>6</sup> (if known) |                                |   |   |                |
| GS<br>↓<br>↓<br>↓<br>↓<br>↓ |                       | WO 01/21647   | 03-29-2001                     | Genset AG                                       |   |                |
|                             |                       | WO 02/18437   | 03-10-2002                     | Hoffman-LaRoche AG                              |   |                |
|                             |                       | WO 02/079753  | 10-10-2002                     | Lion BioScience AG                              |   |                |
|                             |                       | WO 03/013509  | 02-20-2003                     | Melacure Therapeutics                           |   |                |
|                             |                       | WO 02/12178   | 02-14-2002                     | Melacure Therapeutics                           |   |                |
|                             |                       | WO 01/55107   | 08-02-2001                     | Melacure Therapeutics                           |   |                |

|                    |                              |                 |            |
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|  |             | Filing Date              | February 10, 2004 |
|  |             | First Named Inventor     | SHARMA, Shubh D.  |
|  |             | Art Unit                 | 1626              |
|  |             | Examiner Name            |                   |
| Sheet <b>3</b>   | of <b>6</b> | Attorney Docket Number   | 70025-US04-574    |

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| Examiner Initials*     | Cite No. <sup>1</sup> | Document Number                          | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|                        |                       | Number-Kind Code <sup>2</sup> (if known) |                                |   |   |
| GS                     |                       | US- 2003/0109556                         | 06-12-2003                     | Mazur, et al.                                   |   |
|                        |                       | US- 2003/0083228                         | 05-01-2003                     | Carpino, et al.                                 |   |
|                        |                       | US- 2003/0069169                         | 04-10-2003                     | Macor, et al.                                   |   |
|                        |                       | US- 2003/0055265                         | 03-20-2003                     | Binggeli, et al.                                |   |
|                        |                       | US- 2003/0055247                         | 03-20-2003                     | Cosford, et al.                                 |   |
|                        |                       | US- 2003/0004162                         | 01-02-2003                     | Treadway  |   |
|                        |                       | US- 2002/0173512                         | 11-21-2002                     | Moltzen, et al.                                 |   |
|                        |                       | US- 2002/0143141                         | 10-03-2002                     | Chen, et al.                                    |   |
|                        |                       | US- 2002/0137664                         | 09-26-2002                     | Bakshi, et al.                                  |   |
|                        |                       | US- 2002/0072604                         | 06-13-2002                     | Carpino, et al.                                 |   |
|                        |                       | US- 2002/0004512                         | 01-10-2002                     | Bakshi, et al.                                  |   |
|                        |                       | US- 2003/0109556                         | 10-31-2001                     | Mazur, et al.                                   |   |
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|                        |                       | US-                                      |                                |   |   |
|                        |                       | US-                                      |                                |   |   |
|                        |                       | US-                                      |                                |   |   |
|                        |                       | US-                                      |                                |   |   |
|                        |                       | US-                                      |                                |   |   |

| FOREIGN PATENT DOCUMENTS  |                       |   |                                |   |   |                |
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|   |                       | Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known) |                                |   |   |                |
| GS<br> |                       | WO 01/55109 :   | 08-02-2001                     | Melacure Therapeutics                           |   |                |
|   |                       | WO 01/55106 :   | 08-02-2001                     | Melacure Therapeutics                           |   |                |
|   |                       | WO 00/35952:  | 06-22-2000                     | Melacure Therapeutics                           |   |                |
|   |                       | WO 02/068387  | 09-06-2002                     | Merck & Co, Inc.                                |   |                |
|   |                       | WO 02/067869  | 09-06-2002                     | Merck & Co., Inc.                               |   |                |
|   |                       | WO 01/30343 .   | 05-03-2001                     | Merck & Co., Inc.                               |   |                |

|                    |                              |                 |            |
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Substitute for form 1448/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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**Complete if Known**

|                        |                   |
|------------------------|-------------------|
| Application Number     | 10/776,657        |
| Filing Date            | February 10, 2004 |
| First Named Inventor   | SHARMA, Shubh D.  |
| Art Unit               | 1626              |
| Examiner Name          |                   |
| Attorney Docket Number | 70025-US04-574    |

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|-------|---|----|---|
| Sheet | 4 | of | 6 |
|-------|---|----|---|

## U. S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. <sup>1</sup> | Foreign Patent Document   | Publication Date | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | T |
|--------------------|-----------------------|---|------------------|---|---|---|
|                    |                       | Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known) | MM-DD-YYYY       |   |   |   |
| GS<br>↓            |                       | WO 98/10653   | 03-19-1998       | Merck & Co., Inc.                               |   |   |
|                    |                       | WO 00/05373   | 02-03-2000       | Millenium Pharmaceutical                        |   |   |
|                    |                       | WO 99/58501   | 11-18-1999       | Novo Nordisk AS                                 |   |   |
|                    |                       | WO 03/006620  | 01-23-2003       | Palatin Technologies                            |   |   |
|                    |                       | WO 02/064,091   | 08-22-2002       | Palatin Technologies                            |   |   |
|                    |                       | WO 02/079203  | 10-10-2002       | Pfizer, Inc.                                    |   |   |

**Examiner  
Signature**

/Golam Shameem/ (09/05/2006)

|                            |  |
|----------------------------|--|
| <b>Data<br/>Considered</b> | <p>1. All data from the 1990-1991 season were included in the analysis.</p> <p>2. Data from the 1991-1992 season were included in the analysis for the following variables:</p> <ul style="list-style-type: none"> <li>• <b>Age:</b> 18-24, 25-34, 35-44, 45-54, 55-64, 65-74, 75-84, 85-94, 95-104</li> <li>• <b>Gender:</b> Male, Female</li> <li>• <b>Ethnicity:</b> White, Black, Hispanic, Asian, Other</li> <li>• <b>Marital Status:</b> Married, Divorced, Widowed, Single</li> <li>• <b>Education:</b> High School, College, Graduate</li> <li>• <b>Income:</b> \$0-\$14,999, \$15,000-\$24,999, \$25,000-\$34,999, \$35,000-\$44,999, \$45,000-\$54,999, \$55,000-\$64,999, \$65,000-\$74,999, \$75,000-\$84,999, \$85,000-\$94,999, \$95,000-\$104,999, \$105,000-\$114,999, \$115,000-\$124,999, \$125,000-\$134,999, \$135,000-\$144,999, \$145,000-\$154,999, \$155,000-\$164,999, \$165,000-\$174,999, \$175,000-\$184,999, \$185,000-\$194,999, \$195,000-\$204,999, \$205,000-\$214,999, \$215,000-\$224,999, \$225,000-\$234,999, \$235,000-\$244,999, \$245,000-\$254,999, \$255,000-\$264,999, \$265,000-\$274,999, \$275,000-\$284,999, \$285,000-\$294,999, \$295,000-\$304,999, \$305,000-\$314,999, \$315,000-\$324,999, \$325,000-\$334,999, \$335,000-\$344,999, \$345,000-\$354,999, \$355,000-\$364,999, \$365,000-\$374,999, \$375,000-\$384,999, \$385,000-\$394,999, \$395,000-\$404,999, \$405,000-\$414,999, \$415,000-\$424,999, \$425,000-\$434,999, \$435,000-\$444,999, \$445,000-\$454,999, \$455,000-\$464,999, \$465,000-\$474,999, \$475,000-\$484,999, \$485,000-\$494,999, \$495,000-\$504,999, \$505,000-\$514,999, \$515,000-\$524,999, \$525,000-\$534,999, \$535,000-\$544,999, \$545,000-\$554,999, \$555,000-\$564,999, \$565,000-\$574,999, \$575,000-\$584,999, \$585,000-\$594,999, \$595,000-\$604,999, \$605,000-\$614,999, \$615,000-\$624,999, \$625,000-\$634,999, \$635,000-\$644,999, \$645,000-\$654,999, \$655,000-\$664,999, \$665,000-\$674,999, \$675,000-\$684,999, \$685,000-\$694,999, \$695,000-\$704,999, \$705,000-\$714,999, \$715,000-\$724,999, \$725,000-\$734,999, 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\$1,975,000-\$1,984,999, \$1,985,000-\$1,994,999, \$1,995,000-\$2,004,999, \$2,005,000-\$2,014,999, \$2,015,000-\$2,024,999, \$2,025,000-\$2,</li></ul> |
|----------------------------|--|

09/05/2006

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

**(Use as many sheets as necessary)**

**Complete if Known**

|                        |                   |
|------------------------|-------------------|
| Application Number     | 10/776,657        |
| Filing Date            | February 10, 2004 |
| First Named Inventor   | SHARMA, Shubh D.  |
| Art Unit               | 1626              |
| Examiner Name          |                   |
| Attorney Docket Number | 70025-US04-574    |

Sheet 5

**5**

of

2

Attorney Docket Number

70025-US04-574

**U. S. PATENT DOCUMENTS**

[illegible]

## FOREIGN PATENT DOCUMENTS

| Examiner Initials*            | Cite No. <sup>1</sup> | Foreign Patent Document   | Publication Date | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | † |
|-------------------------------|-----------------------|---|------------------|---|---|---|
|                               |                       | Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known) | MM-DD-YYYY       |   |   |   |
| GS<br><br>↓<br><br>↓<br><br>↓ |                       | WO 02/47670   | 06-20-2002       | Pfizer, Inc.                                    |   |   |
|                               |                       | WO 86/38471   | 12-05-1996       | Pfizer, Inc.                                    |   |   |
|                               |                       | WO 02/085925  | 06-12-2003       | Proctor & Gamble Co.                            |   |   |
|                               |                       | WO 01/12176   | 02-22-2001       | Sanofi Synthelabo                               |   |   |
|                               |                       | WO 01/23392   | 04-05-2001       | Trega BioSciences, Inc.                         |   |   |
|                               |                       | WO 01/21634   | 03-29-2001       | Trega BioSciences, Inc.                         |   |   |

Package  
4 of 4

|                       |                              |                    |            |
|-----------------------|------------------------------|--------------------|------------|
| Examiner<br>Signature | /Golam Shameem/ (09/05/2006) | Date<br>Considered | 09/05/2006 |
|-----------------------|------------------------------|--------------------|------------|

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STATEMENT BY APPLICANT**

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|                        |                   |
|------------------------|-------------------|
| Application Number     | 10/776,657        |
| Filing Date            | February 10, 2004 |
| First Named Inventor   | SHARMA, Shubh D.  |
| Art Unit               | 1626              |
| Examiner Name          |                   |
| Attorney Docket Number | 70025-US04-574    |

Sheet

6

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6

**NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|--------------------|-----------------------|---|----------------|
| GS                 |                       | "Synthetic Peptides: A Users Guide," GA Grant, editor, W.H. Freeman & Co., New York, 1992 (pp. 11-24)   |                |
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|--------------------|------------------------------|-----------------|------------|
| Examiner Signature | /Golam Shameem/ (09/05/2006) | Date Considered | 09/05/2006 |
|--------------------|------------------------------|-----------------|------------|

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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